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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,307	12/08/2003	Pooneh Mohajer	MHJ-03902/16	2168
25006	7590	06/28/2005	EXAMINER	
GIFFORD, KRASS, GROH, SPRINKLE & CITKOWSKI, P.C PO BOX 7021 TROY, MI 48007-7021			FLANAGAN, BEVERLY MEINDL	
			ART UNIT	PAPER NUMBER
			3739	
DATE MAILED: 06/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/730,307

Applicant(s)

MOHAJER, POONEH

Examiner

Beverly M. Flanagan

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

  
BEVERLY M. FLANAGAN  
PRIMARY EXAMINER

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/5/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement filed March 5, 2004 has been made of record and the references cited therein have been considered by the examiner.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "sheet material" in line 1. There is insufficient antecedent basis for this limitation in the claim, as independent claim 1, from which claim 5 depends, recites "flexible film material". Similarly, claim 9 recites "sheet material" in line 1. There is insufficient antecedent basis for this limitation in the claim, as independent claim 7, from which claim 9 depends, recites "sheet cover".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6, 7, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Francois (U.S. Patent No. 6,432,048).

**In regard to claims 1, 6, 7 and 11**, Francois teaches a sheath for a speculum 30 where the sheath comprises a disposable tubular member 33 that has a pair of distal pockets 34 and 35 that are dimensioned to receive the distal ends 36 and 37 of one of the blades 31 and 32 of speculum 30 (see Figures 5 and 6 and col. 4, lines 30-40). Figures 5 and 6 show that the tubular member 33 has open proximal end distal ends and that the pockets 34 and 35 are formed on the interior wall of tubular member 33 at diametrically opposed points. Figures 5 and 6 also show that pockets 34 and 35 have openings at their proximal ends. **With further respect to claim 7 and in regard to claims 2 and 10**, Figures 5 and 6 show that pockets 34 and 35 have pointed tips formed forward of the distal ends to prevent rollback (see also col. 4, lines 30-45). **In regard to claim 4**, Figures 5 and 6 show that tubular member 33 has an enlarged diameter section at the proximal end.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francois (U.S. Patent No. 6,432,048).

**In regard to claims 3 and 8**, Francois is silent as to a lubricated coating on the exterior of tubular member 33. However, the examiner takes official notice that the practice of applying a lubricated coating to a speculum prior to its insertion is well known and conventional. Furthermore, since there are many prior art examples of sheaths or covers for speculums, the examiner similarly takes official notice that applying a lubricated coating to a sheath or cover on a speculum prior to its insertion is also well known in the art. Accordingly, it would have been obvious for one of ordinary skill in the art at the time the invention was made to apply a lubricated coating on the tubular member 33 of Francois prior to insertion of the tubular member 33 and speculum 30.

Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francois (U.S. Patent No. 6,432,048) in view of Mayes (U.S. Patent No. 5,460,165).

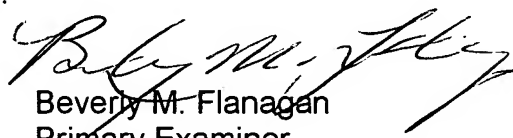
**In regard to claims 5 and 9**, Francois is silent as to the tubular member 33 being formed from latex. However, Mayes discloses a similar sheath 64 for covering a speculum 10 where sheath 64 is preferably constructed from latex (see col. 4, lines 1-8). Mayes thus demonstrates that sheaths for speculums that are fabricated from latex are well known in the art. Accordingly, it would have been obvious for one of ordinary skill in the art at the time the invention was made to fabricate the tubular member 33 of Francois from latex, in the manner disclosed by Mayes.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Beverly M. Flanagan whose telephone number is (571) 272-4766. The examiner can normally be reached on Mondays, Tuesdays and Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Beverly M. Flanagan  
Primary Examiner  
Art Unit 3739

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